UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

KEVIN DRAKE and LORI DRAKE, individually and as next friend of J.D. Plaintiffs, v. ALLERGAN, INC. Defendant.	:	Case No. 2:13-cv-234

Opinion and Order

Plaintiff J.D. is a minor with cerebral palsy whose parents, Kevin and Lori Drake, filed claims individually and as next friend of J.D. against Defendant Allergan, Inc. ("Allergan"), the manufacturer of Botox. Plaintiffs' claims arise from injuries J.D. sustained that allegedly resulted from a Botox injection administered to treat his lower limb spasticity. Both parties have submitted pre-trial motions to exclude expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

For the following reasons the Court **denies** Plaintiff's Motion to Exclude Defendant's Expert Michael S. Duchowny, M.D., ECF No. 91, **grants in part** and **denies in part** Defendant's Motion to Exclude Expert Testimony of David A. Kessler, M.D., ECF No.

92, and **grants in part** and **denies in part** Defendant's Motion to Exclude Expert Testimony of Anna Hristova, M.D., ECF No. 93.

I. Legal Standard

Admissibility of expert testimony is governed by Federal Rule of Evidence 702, which states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702 requires a district court to ensure that scientific or technical evidence is both relevant and reliable. *Kumho Tire v. Carmichael*, 526 U.S. 137, 147 (1999); *Daubert*, 509 U.S. at 589. The evidentiary reliability of the proposed testimony depends on its scientific validity. *Daubert*, 509 U.S. at 590 n.9. The subject of an expert's testimony must be "scientific knowledge." *Id.* at 590. "Scientific" implies grounding in the methods and procedure of science while "knowledge" connotes more than subjective belief or unsupported speculation but need not be certainty. *Id.* In assessing reliability, in addition to the factors set forth in Rule 702, a district court may consider:

> (1) whether a theory or technique has been or can be tested; (2) whether the theory or technique has been

> subjected to peer review and publication; (3) the technique's known or potential rate of error and the existence and maintenance of standards controlling the technique's operation; and (4) whether a particular technique or theory has gained general acceptance in the relevant scientific community.

United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007) (internal quotation omitted).

As for relevance, in order to assist the trier of fact proposed expert testimony must be sufficiently tied to the facts of the case to "make the existence of any fact that is of consequence to the determination of the action more or less probable than it would be without the evidence." Fed. R. Evid. 401. The question of relevance has also been described as "fit." *Daubert*, 509 U.S. at 591. Expert testimony that does not relate to any issue in the case is not relevant and, therefore, not helpful. *Id.*

The court must make a preliminary assessment of whether the reasoning and methodology underlying the testimony is scientifically valid and whether that reasoning or methodology can properly be applied to the facts in issue. *Id.* at 592-93. The inquiry envisioned by Rule 702 focuses solely on principles and methodology, not on the conclusions they generate. *Id.* at 595.

The party proffering expert testimony has the burden of establishing its admissibility by a preponderance of proof but

the court is the ultimate gatekeeper. *Id.* at 592 n.10; *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007). The Supreme Court emphasized the "liberal thrust" of the Federal Rules of Evidence, favoring admissibility of expert opinion testimony. *Daubert*, 509 U.S. at 588. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* at 596.

Nevertheless, expert testimony should be excluded if it is "speculative or conjectural." *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 311 (2d Cir. 2008) (quoting *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996). Neither *Daubert* nor the Federal Rules of Evidence requires a district court to admit opinion evidence that is "connected to existing data by only the *ipse dixit* of the expert" if the court concludes that "there is simply too great an analytical gap" between the data and the proffered opinion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

II. Plaintiffs' Motion to Exclude Defendant's Expert Michael S. Duchowny, MD

Plaintiffs move to exclude Dr. Michael S. Duchowny's testimony entirely[1] for three reasons: 1) his opinion that Botox injections cannot cause seizures is based on a misreading of selected literature and ignores a significant amount of evidence to the contrary, 2) his opinion that J.D. has not suffered seizures but instead experienced an allergic reaction is unsupported by the evidence and is contrary to the opinion of every treating doctor and every other medical expert designated by either party, and 3) Dr. Duchowny is not qualified to diagnose allergic reactions.

A. Dr. Duchowny's Opinion Concerning the Causal Relationship Between Botox and Seizures

Plaintiffs argue that Dr. Duchowny's opinions about general causation are so far removed from the underlying facts and the available scientific literature that they are unreliable and therefore inadmissible. Plaintiffs suggest Dr. Duchowny's opinion regarding the causal relationship between Botox and seizures in general is based "almost entirely" on three sources:

[1] Allergan intends to ask Dr. Duchowny about opinions other than those Plaintiffs criticize. Even if the Court were to exclude these three opinions, there would be no reason to prevent Dr. Duchowny from testifying entirely as long as his other opinions are relevant and reliable. Plaintiffs have not presented any argument as to why the other opinions that were not discussed in their motion should be excluded. Plaintiffs' motion, therefore, is overbroad and the Court will only consider excluding the individual opinions.

1) the Coté article, 2) letters to the editor written on behalf of Allergan to criticize the Albavera-Hernandez epidemiology study, and 3) the Naidu article. Plaintiffs criticize Dr. Duchowny's reliance on and interpretation of these articles and claim he failed to address a plethora of evidence contrary to his opinion that Botox cannot cause seizures.

Allergan counters that this characterization of the source of Dr. Duchowny's opinions is false. According to Allergan, Dr. Duchowny actually relies on a number of studies Plaintiffs ignore in addition to his significant clinical experience with Botox, spanning more than ten years and thousands of patients. Allergan also argues Dr. Duchowny's experience is similar to that of other witnesses in this case, including Dr. Scott Benjamin, J.D.'s physiatrist who injected J.D. with Botox, and Dr. Janice Brunstrom-Hernandez, another expert who has treated over one thousand children with cerebral palsy with Botox injections. Finally, Allergan points out that Dr. Duchowny actually received and considered all but one source Plaintiffs identify and argue the source he did not consider was unremarkable.

Plaintiffs do not dispute and the Court agrees that Dr. Duchowny is well-qualified as an expert in neurology. Dr. Duchowny is a Senior Staff Attending Physician in Neurology at the Miami Children's Hospital and Professor of Clinical

Neurology at the University of Miami Leonard Miller School of Medicine. He directs the Comprehensive Epilepsy Program and the Neurology Training Programs at Miami Children's Hospital. Dr. Duchowny has over thirty years of clinical experience in the diagnosis, prognosis, and management of children with cerebral palsy and epilepsy. He has won multiple awards and honors and has authored more than a hundred articles, dozens of book chapters, and several books.

Dr. Duchowny's opinions regarding the relationship between Botox and seizures are made in the context of criticizing Dr. Hristova's causation opinions rather than as a standalone opinion. *See* Section IV below. Dr. Duchowny opines that it is "doubtful" that Botox causes seizures because there is no established link between the two based on his clinical experience and his reading of the scientific literature. Duchowny Rep. at 14.

The Court is mindful that it is difficult to prove a negative, which in this case would be a lack of evidence supporting a causal connection between Botox injection and seizures. The Court also notes that causation in this case is a hotly disputed issue. While Dr. Hristova connects the dots between various pieces of evidence that suggest that Botox can cause seizures, there is no definitive evidence regarding causation that Dr. Duchowny has failed to take into account.

Dr. Duchowny relies on other articles to support his opinions but he does rely on the articles Plaintiffs identify (*i.e.* the Coté article, the Naidu article, and the letters critical of Albavera-Hernandez) to undermine Dr. Hristova's opinion on causation. The experts' disagreement about the meaning and importance of these studies is not a reason to exclude Dr. Duchowny's testimony entirely. Dr. Duchowny's proposed testimony is based on sufficient facts and data: his own extensive clinical experience and the scientific literature he reviewed. Plaintiffs' arguments about the particular articles to which he refers go to weight rather than admissibility and Plaintiffs are free to raise them all during cross-examination.

B. Dr. Duchowny's Opinion Concerning Whether J.D. Has Suffered Seizures

Plaintiffs argue that because Dr. Duchowny's general causation opinion is questionable his specific causation opinion is also unreliable. Moreover, Plaintiffs claim that in reaching his conclusion that J.D. did not experience seizures, Dr. Duchowny improperly disregarded the diagnoses of all of J.D.'s treating physicians and discredited J.D.'s EEG, which included epileptiform discharges.

Allergan counters that Plaintiffs overstate Dr. Duchowny's opinion with respect to the nature of J.D.'s episodes. Dr.

Duchowny does not claim that J.D. certainly *did not* experience seizures. Rather Dr. Duchowny opines that he cannot conclude with a reasonable degree of medical certainty that J.D. *did* experience seizures or that J.D. has epilepsy. In other words, he does not completely exclude the possibility and even assumes for argument's sake that J.D. did experience seizures when evaluating the rest of Dr. Hristova's report. Allergan argues that Dr. Duchowny's inability to opine conclusively is supported by the medical records and points out that for months J.D.'s doctors considered his episodes likely to be the result of allergic reactions. Finally, Allergan argues that Dr. Duchowny does not ignore the diagnoses of other doctors or the EEG but rather comes to different conclusions than the other doctors and gives the EEG different weight in his analysis.

Dr. Duchowny supports his opinion regarding J.D.'s episodic events by raising several specific criticisms based on his medical training that make him skeptical that seizure was an appropriate diagnosis. Duchowny Rep. at 9-10. Dr. Duchowny did not disregard the EEG. He simply did not consider it diagnostic by itself. Dr. Duchowny relied on J.D.'s medical records and his own medical training to interpret the symptoms J.D. experience. That Dr. Duchowny's conclusion is different from the other doctors' conclusions is not a sufficient reason to exclude his testimony because in its role as gatekeeper a court

is not concerned with experts' conclusions but rather their methods. *Daubert*, 509 U.S. at 595. Plaintiffs will be free to raise all of their criticisms of his conclusion through cross-examination and competing testimony.

C. Dr. Duchowny's Qualification to Diagnose Allergic Reactions

Finally, Plaintiffs argue that Dr. Duchowny is unqualified to opine that J.D. experienced an allergic reaction because he is not an allergist and he refers patients to specialists in his own practice. Allergan does not dispute that Dr. Duchowny is not an allergist but notes he has had experience in the area as part of his overall medical training. Dr. Duchowny is not required to specialize in allergic reactions in order to opine that J.D. may have experienced one since he bases his opinion on his own medical training and clinical experience.

All Dr. Duchowny's challenged opinions are admissible for the reasons stated above. Accordingly Plaintiff's Motion to exclude Dr. Duchowny's testimony is **denied**.

III. Defendant's Motion to Exclude Expert Testimony of David A. Kessler, MD

Allergan does not dispute Dr. Kessler's qualification as an expert and the Court finds that he is well-qualified. Dr. Kessler has both medical and legal training. He was Commissioner of the FDA from the time he was appointed in 1990 until February 1997, serving under both Presidents Bush and

Clinton. After he left the FDA he became the dean of the Yale Medical School and then served as Dean of the medical school of the University of California, San Francisco where he remains a tenured faculty member. He has won a long list of honors and awards and has authored or edited several books and dozens of articles.

Allergan seeks to prevent Dr. David A. Kessler from 1) instructing the jury on the law or offering legal conclusions, 2) from narrating the evidence or regurgitating facts, and 3) from drawing inferences about the knowledge, motives, or intent of individuals or organizations. There does not appear to be any significant controversy that these categories of testimony are generally not proper subjects for expert testimony. *See, e.g. Hygh v. Jacobs*, 961 F.2d 359, 363 (2d. Cir. 1992) (noting that expert testimony that expresses a legal conclusion must be excluded); *Highland Cap. Mgmt., L.P. v. Schneider*, 379 F. Supp. 2d. 461, 468-69 (S.D.N.Y. 2005) (reasoning that though experts must rely on facts or data in forming their opinions they cannot be presented to the jury solely for the purpose of constructing a factual narrative); *In re Fosamax Products Liability Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (excluding testimony about the knowledge, motivations, intent, state of mind, or purposes of the defendant, the FDA, or FDA officials).

Plaintiffs raise an overarching objection that these issues are not the proper subject for a motion to exclude expert testimony and would be better addressed as objections at trial. Some courts have issued general instructions before trial limiting Dr. Kessler or other experts from getting into topics their testimony may or may not touch on based on the contents of their reports. For example, in a case fairly similar to this one, the court in *Wells v. Allergan*, No. CIV-12-973-C, 2013 WL 7208221, at *1-2 (W.D. Okla. Feb 4, 2013) held that Dr. Kessler could testify as to the law governing FDA regulations, the facts from which a jury could infer intent, and relevant, non-cumulative facts he relied upon in forming his opinions but could not testify as to the elements of strict liability or negligence under Oklahoma law, speculate about the state of mind of relevant actors, or rehash admissible evidence. *See also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 628-32 (S.D. W. Va. 2013); *Georges v. Novaritis Pharm. Corp.*, No. CV 06-5207 SJO (VBKx), 2012 WL 9064768, at *9-10 (C.D. Cal. Nov. 2, 2012); *Fosamax*, 645 F. Supp. 2d. at 192.

Other courts have noted that these types of challenges are inappropriate in a *Daubert* motion but ultimately go on to analyze what they anticipate the experts will testify about under a motion *in limine* analysis. *See In re Actos (Pioglitazone) Prod. Liability Litig.*, No. 12-cv-00064, 2014 WL

120973, at *2 (W.D. La. Jan. 10, 2014) (defendants' arguments conflated true *Daubert* challenges with more general *limine*-type challenges); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liability Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6302287, at *11 (S.D. Ill. Dec. 16, 2011) (defendants sought to exclude Dr. Kessler's testimony for reasons inapplicable under *Daubert* and more properly brought as motions *in limine* or objections at trial).

As an initial matter, the Court notes that the general challenges Allergan raises are obviously correct and apply equally to any expert in this case, including, in particular, Dr. David W. Feigal, Jr., Allergan's regulatory expert. No expert shall be permitted to usurp the role of the court and instruct the jury on state tort law, narrate or regurgitate facts in a way that crosses the line into closing argument territory, or speculate about other individual's or entity's motives, knowledge, or intent.

At trial, counsel for either party may object if an expert's testimony crosses the line. The Court will consider, for example, whether a recitation of facts is properly the basis of the expert's opinion or has transitioned into mere regurgitation, or, for example, whether a description of Allergan's actions which might lead the jury to conclude malice or recklessness crosses over to an opinion about intent.

The Court is necessarily limited in its ability to make specific findings because drawing the line between acceptable and unacceptable testimony in these categories inherently depends on the nature of the actual testimony. However, the Court notes that Dr. Kessler may testify about the FDA's regulatory scheme in general, FDA practices and procedures, Allergan's compliance with FDA regulations, the FDA's relationship with pharmaceutical companies, and the standard of care for the pharmaceutical industry based on his training and experience. Dr. Kessler is not permitted to offer testimony about legal definitions and legal duties under state law. Next, Dr. Kessler may testify about the facts on which he relies in forming his opinions assuming they are relevant and non-cumulative. Finally, Dr. Kessler may be permitted to testify about another party's knowledge if a jury would not otherwise understand the importance of certain facts without the benefit of his expertise – for example what is or is not common knowledge in the pharmaceutical company community based on his experience at the FDA.

Accordingly Allergan's Motion is **granted** to the extent it sought the general guidance given above and **denied** to the extent that some objections will have to be raised at trial.

IV. Defendant's Motion to Exclude Expert Testimony of Anna Hristova, MD

Allergan moves to exclude Plaintiffs' expert Dr. Anna Hristova from offering four opinions: 1) an opinion that Botox caused J.D. to experience seizures, 2) an opinion on the adequacy of the Botox label, 3) an opinion on the permissibility of communications with doctors about potential drug effects, and 4) an opinion on Allergan's alleged influence on the scientific literature concerning Botox.

A. Dr. Hristova's Opinion that Botox Caused J.D. to Experience Seizures

Allergan does not dispute Dr. Hristova's qualifications to offer an opinion on causation and the Court finds she is well-qualified. Dr. Hristova is a board-certified neurologist with sub-specialties in movement disorders and neurophysiology. She has won a long list of awards and honors and has authored dozens of articles and a book chapter. Dr. Hristova has training in electrophysiology and extensive expertise in injecting botulinum toxin to treat neurological conditions.

Allergan's primary argument as to why Dr. Hristova's opinion regarding causation should be excluded is that she cannot explain *how* Botox could cause seizures. Instead she offers a "smorgasbord of theoretical mechanisms" that have not been tested, published, or subjected to the scrutiny of peer

review.[2] ECF No. 93-1 at 5. Allergan also criticizes Dr. Hristova's reliance on animal studies and adverse event reports.[3]

In fact, Dr. Hristova's theories have been published in a peer-reviewed journal. *See* Anna H. Hristova et al., *Severe Nervous System Complications after Botulinum Type A Therapy: Three Case Reports with Reviews of FDA-Reported Nervous System Effects*, 4 PM&R 613 (Aug. 2012). But even if they had not, it is not necessary for an expert to know the exact mechanism of how a drug causes an injury in order for her opinion on causation to be reliable and admissible. *See, e.g.*, *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 2971550, at *3 (D. Vt. July 20, 2012)); *Deutsch v. Novaritis Pharm. Corp.*, 768 F. Supp. 2d 420, 438 (E.D.N.Y. 2011); *Fosamax*, 645 F. Supp. 2d at 183 (S.D.N.Y. 2009). Allergan's argument is misplaced in this case because medical science does not know a great deal about the

[2] Allergan relies heavily on *In re Rezulin Product Liability Litigation*, 369 F. Supp. 2d 398 (S.D.N.Y. 2005) to support its argument in favor of excluding Dr. Hristova's testimony because "[s]titching together theories that on their own might separately satisfy the Daubert reliability criteria does not generate a reliable theory unless the *entire causal chain* also satisfies the *Daubert* reliability criteria." ECF No. 93-1 at 10. Dr. Hristova is not opining about a causal chain as the experts in *Rezulin* proposed to do. Dr. Hristova claims Botox causes seizures by affecting the brain itself rather than opining that Botox causes some intermediate state in the body which then theoretically causes seizures. The reasoning of *Rezulin* is not on point here.

[3] Allergan has filed a motion *in limine* to exclude the adverse event reports and the animal studies. The Court will issue separate opinions addressing those categories of evidence.

mechanism of action for seizures in general. An expert may not present theories that are little less than rank speculation but she need not be certain in order for her opinions to be admissible. *See Daubert*, 509 U.S. at 590.

Moreover, an expert is not required to back her opinion with published studies that unequivocally support her conclusions. *Amorgianos v. Nat'l Railroad Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). In some instances, epidemiological evidence combined with other types of evidence are sufficient when packaged together. The Court finds the reasoning in a multi-district products liability litigation opinion from the Southern District of New York instructive here. In *Fosamax*, the drug manufacturer argued that the plaintiff's experts lacked a reliable foundation for opinions based upon "mere case reports and case series, prevalence studies, adverse event reports, inapplicable animal studies, and unproven hypotheses about the mechanism or mechanisms through which" the drug at issue supposedly caused the alleged injury. 645 F. Supp. 2d at 175. The court found this evidence sufficient and, for example, admitted testimony of a proposed oral maxillofacial expert that was based on her clinical experience, case reports, and a proposed mechanism that was "biologically plausible." *Id.* at 179.

There is no definitive evidence that Botox causes or does not cause seizures, perhaps in part because scientists cannot ethically experiment on humans due to the lethal nature of the toxin. *See In re Rezulin Product Liability Litig.*, 369 F. Supp. 2d 398, 406 (S.D.N.Y. 2005) (noting that although the clinical trial is the "gold standard" for determining causation, such studies are not always available when ethical constraints preclude exposing human beings to agents known to be toxic). However, the evidence on which Dr. Hristova relies is very similar to the evidence the court found sufficient in *Fosamax*.

First, the most important piece of evidence is the Albavera-Hernandez study, which is a meta-analysis in which the authors found an association between botulinum toxin type A and seizures in children with cerebral palsy. The parties dispute the accuracy and reliability of this study and Dr. Hristova does acknowledge that this study may have some limitations. However, those issues go to weight and may be raised either on cross-examination or through competing testimony from other experts. The Albavara-Hernandez study is an important piece of epidemiological evidence on which Dr. Hristova relies and there is no competing study that failed to find an association.

Next, Dr. Hristova relies on Allergan's 2004 and 2012 Seizure Disorder Safety Analysis, which each included a compilation of reports from children experiencing seizures after

receiving a Botox injection. The 2004 report presented three patients who experienced a positive rechallenge, meaning the side effect disappeared when the drug was withdrawn but reappeared when the drug was reintroduced. Plaintiffs argue these case reports should be given extra weight because a positive rechallenge is "a very significant term of art in the fields of spontaneous adverse event reporting and epidemiology." ECF No. 108 at 10.

Case reports lack controls so any causal attribution based on adverse event reports must be regarded with caution. *Rezulin*, 369 F. Supp. 2d. at 406. Moreover the FDA itself warns that adverse event reports do not necessarily demonstrate a causal connection. *See* 21 C.F.R. § 314.80(k). While Plaintiffs concede that courts have held that causation opinions should not be based *solely* on adverse event reports, they correctly argue adverse event reports are nevertheless relevant when combined with other evidence, particularly epidemiological evidence. Here the adverse event reports in general and the positive rechallenges in particular, lend support to Dr. Hristova's opinion.

Next, Dr. Hristova relies on animal studies to support her causation theories. Animal studies have the advantage of being conducted as true experiments but extrapolation from animal studies cannot be done uncritically. *Rezulin*, 369 F. Supp. 2d.

at 407. Plaintiffs also concede that courts are reluctant to allow causation testimony based solely on animal studies but argue relying on them may be proper if there is other corroborating evidence of causation as there is here. Here, the animal studies are some of the "pieces of the scientific puzzle" that contribute to the reliability of Dr. Hristova's opinion. *Fosamax*, 645 F. Supp. 2d at 187.

Next, there is at least some evidence that Dr. Hristova's causation opinion is biologically plausible. In his deposition, Allergan's Vice President of Neurotoxin research conceded that it was biologically plausible that Botox can cause seizures. Aoki Dep. Tr. 32:20-23 (Q "[M]y question is is triggering of seizures due to peripheral BOTOX injections biologically plausible? A Yes."). Moreover, the specific potential mechanisms Dr. Hristova has proposed were sufficiently plausible to be published in a peer-reviewed journal. Although the proposed mechanism in *Fosamax* was more widely reported than Dr. Hristova's, the existence of a biologically plausible mechanism bolsters the reliability of here proffered opinions on causation. *Fosamax*, 645 F. Supp. 2d at 183.

Finally, Dr. Hristova relies on her personal experience injecting Botox, her knowledge of the field, and the fact that black box warning on the label does contain some mention of seizures. Put together, all of these pieces of evidence make

Dr. Hristova's opinion sufficiently reliable to be presented to a jury.

It is also important to note that at least one other court has considered Dr. Hristova's opinions on the relationship between Botox and seizures and held that Dr. Hristova's position is based on reliable studies and methodology. *Wells*, 2013 WL 7208221, at *3. The Court is aware of no other court that has excluded her testimony.

Finally, Allergan argues that Dr. Hristova's theories do not "fit" because she cannot say which one occurred with in J.D.'s case. This argument is misplaced. Dr. Hristova is doing more than randomly guessing about theoretical mechanisms as Allergan suggests. She has specialized knowledge based on her medical training and her review of the literature. A juror without medical training would not be likely to speculate that Botox may travel through the blood or that it may travel through retrograde axonal transport.

Just as Plaintiffs will be free to cross-examine Dr. Duchowny, so too will Allergan be free to raise all of its critiques through cross-examination. Accordingly, Allergan's motion to exclude Dr. Hristova's opinion that Botox caused J.D.'s seizures is **denied**.

B. Dr. Hristova's Opinion Concerning the Adequacy of the Botox Label

Allergan seeks to exclude any testimony by Dr. Hristova suggesting that the Botox label is inadequate because it does not state the number of seizures that have been reported following Botox treatment. Dr. Hristova admits she is not an expert in pharmaceutical labeling and has no relevant experience. Therefore, Allergan argues, she is not qualified to offer any opinion on the adequacy of the Botox label. Allergan emphasizes that Dr. Hristova never treated, examined, or even personally met J.D. and there is no indication that she has ever practiced medicine in Vermont.

Plaintiffs argue that virtually every court that has considered the issue has allowed prescribing doctors to testify regarding the adequacy of a drug warning from the doctor's point of view. Moreover Plaintiffs contend that Dr. Hristova will not be testifying about whether the label complied with FDA regulations.

Dr. Hristova may testify about how she would have interpreted the Botox label and the effect the label would have had on her as a member of the medical community treating patients with Botox. Plaintiffs agree that Dr. Hristova will not testify about whether the label complied with FDA regulations. The Court notes that this limit includes what the

label could or should have contained under those regulations. Accordingly, Allergan's motion to exclude Dr. Hristova's opinion on the adequacy of the Botox label is **granted in part** and **denied in part**.

C. Dr. Hristova's Opinion Concerning the Permissibility of Communications with Doctors about Potential Drug Effects

Allergan seeks to exclude Dr. Hristova's opinions regarding what information the FDA would allow Allergan to share with physicians concerning off-label uses of Botox because, again, she is not an expert in in FDA regulations. Plaintiffs state that Dr. Hristova will not be eliciting testimony on direct examination regarding FDA regulations but argue she should be permitted to defend herself on cross-examination if Allergan raises the issue by contending it is prohibited from warning about the 8 unit per kilogram dose. If Allergan opens the door on cross-examination, Dr. Hristova will be permitted some latitude to defend herself. However she may not testify about whether sharing particular information would or would not violate the FDA's ban on off-label promotion.

Accordingly, Allergan's motion to exclude Dr. Hristova's opinion on the permissibility of communications with doctors about potential drug effects is **granted**.

D. Dr. Hristova's Opinion Concerning Allergan's Alleged Influence on the Scientific Literature

Allergan seeks to exclude Dr. Hristova's opinions regarding its alleged influence on the scientific literature concerning Botox. According to Allergan, opinions about the motive and intent of other authors are not a proper subject for expert testimony in general and Dr. Hristova is not an expert in determining alleged influence and bias in the literature. Moreover she did not perform a systematic analysis of the literature nor did she adequately demonstrate that sponsorship by Allergan influenced the authors in some way.

Plaintiffs argue Allergan influences the literature by attacking articles questioning the safety of Botox and by financing and influencing the majority of favorable literature. Dr. Hristova has allegedly experienced Allergan's "all-encompassing influence" firsthand. ECF No. 108 at 18. Moreover, she uses statistics to demonstrate how the results of one study were skewed in favor of Botox and this specialized knowledge will be helpful to the jury.

Opinions about the motive and intent of other actors is not a proper subject of expert testimony where a jury is capable of drawing its own inferences from the evidence. *See* Section III above. Dr. Hristova, like the other experts in this case, generally may not speculate about another actor's motives or

intentions. However, she may testify about any personal or firsthand knowledge she has regarding Allergan's influence or attempted influence on her or other authors. She may also testify as a member of the medical community about her perception or understanding of the pattern of conduct of pharmaceutical companies to attempt to influence acceptance of their products. Accordingly, Allergan's motion to exclude Dr. Hristova's opinion on Allergan's alleged influence on the scientific literature is **granted in part** and **denied in part**.

Dated at Burlington, in the District of Vermont this 23rd day of October, 2014.

/s/ William K. Sessions III
William K. Sessions III
District Court Judge